Attachment G

Federal Institute
for Hygienic Consumer Protection and Veterinary Medicine

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Export of Meat Products to the USA
Specifically: Comment by the Federal Republic of Germany on the Final FSIS Report dated 6 November 2001 (Audit Report for Germany July 18 – August 6, 2001)

My Dear Dr. Prucha,

We hereby send you the enclosed Communication from the Federal Republic of Germany on the above-mentioned audit report for your information.

Cordially,
By Order

[Signature illegible]

Dr. Hoppe

Communication

by the Federal Republic of Germany to the Food Safety and Inspection Service Concerning the Audit Report for Germany dated 06 November 2001

Preface:

1. This Communication is based on the comments coordinated between the monitored enterprises and the veterinary authorities that are responsible on site as well as the licensing authorities (supervisors) as well as the deficiency correction reports. The Audit Report mentions the deficiencies that were observed on site and that were addressed during the particular final conferences, although – and this is noted with a critical emphasis – this was frequently formulated in an unsystematic and generalizing fashion, in other words, in too much of a lump-sum approach. It is therefore suggested for the future that a more detailed list of deficiencies with a precise description of the deficiency be drafted for each monitored enterprise.

2. Upon critical evaluation of the described shortcomings, one can establish without any doubts that the overwhelming number of deficiencies involves so-called paperwork deficiencies and not any significant genuine hygienic deficiencies that could be the source of a health hazard to the consumer. Such shortcomings that were observed during the inspection as a rule were immediately corrected; others such as, for example, insufficient training of personnel, have in the meantime been remedied. It must, however, be noted at this point that all of the listed shortcomings are to be sanctioned according to the Community Law of the European Union. The concerns of the FSIS, expressed prior to the audit, likewise are no longer justified because one can just about rule out any health impairment of the consumer due to genuine and grave hygienic shortcomings.

3. The shortcomings under discussion have in the meantime been remedied. Here are further details:

With respect to Enterprise **A/IV/10 Meica Ammerländische Fleischwarenfabrik** in Edewecht:

The following were challenged accordingly:

A. the HACCP Plan:

1. The HACCP Plan, it was charged, does not adequately define the boundary values, the measurement methods and the measurement frequency at the individual HACCP's;

2. the HACCP Plan, it was charged, was not examined for its functional efficiency and it was noted that it had not been validated;

- the HACCP Plan, it was charged, does not contain any adequate description of the verification measures and the frequency with which these measures are implemented. The company personnel, it was noted, do not carry out constant verification measures (on-going verification) in the proper manner;

3. the monitoring measures at the CCP's, it was noted, were not being documented.

B. Official Supervision:

1. Official supervision was not done daily and monitoring from the start of work at the plant and during the second shift, it was charged, is not adequate;

2. the constant verification measures (on-going verification) reportedly are not being adequately carried out by Supervision.

Comment on A.1:
The HACCP Plan of Firma Meica has been spelled out very precisely, noting as to the methods that are to be employed and how frequently the prescribed monitoring parameters must be measured and documented at the CCP's.

Moreover, the boundary values are exactly defined at all CCP's and the measures that are to be taken when the boundary value is exceeded are spelled out. Corrective measures are governed by the provisions of § 417.2 of FSIS Directive 500.1, Attachment 1. One cannot recognize any deficiency here.

Note:

If the input temperature measurement considered as a deficiency by the FSIS is construed according to the Minimax principle, then this shortcoming has been remedied, although one might argue whether a Minimax measurement with many measurement points might not make more sense than an exact temperature documentation of just a few measurement points, in particular, because the HACCP system rests on the basis of the boundary value principle.

With respect to A.2:

Validation according to the Definition of the Codex Alimentarius, second edition, supplement to Volume 1, B-1997 is the "receipt of evidence that the elements of the HACCP Plan are in effect." FSIS Directive 5000.1, Attachment 1, in § 417.4, also describes "initial validation" as a summary of measures that must be mentioned in order to determine whether the HACCP Plan works as intended. Main points in validation – if the term is correctly interpreted in the Codex – must be the bacteriological safety in commercially sterile canned products. According to the view held here, the HACCP Plan is validated in terms of bacteriological stability when the monitoring is done in accordance with the provisions of the "Code of Federal Regulations -- § 318, Subpart 6." Firma Meica has regularly performed these monitoring functions for many years and prior to every boiling. Moreover, the effectiveness of the HACCP Plan has for years been validated with the help of external and internal bacteriological exams of the finished products. The validation of the HACCP Plan regarding the prevention of foreign bodies and residues naturally can be accomplished only in a restricted manner by means of regular checks on the integrity of materials that come into contact with foods (foreign bodies) as well as random sample examinations of finished products and, above all, analysis of official challenges and consumer complaints. All mentioned measures are documented and are part of the HACCP Plan. One cannot recognize a deficiency in the validation of the HACCP Plan of Firma Meica to the extent that the definition of the Codex and of the FSIS Directive were used as basis.

With respect to A.3:

According to the definition of the Codex Alimentarius, verification consists of "methods, processes, analyses and other evaluations implemented in addition to supervision by means of which it is to be determined whether the HACCP Plan is being complied with." According to the view held here, verification cannot be neatly separated from the validation of the HACCP Plan. Verification, in particular, comprises control measures as part of the monitoring that is actually done, in other words, checks on measurements and measurement frequency on the HACCP. This is also indicated in FSIS Directive 5000.1 in § 417.4, No. 2 under the heading of "On-Going Verification Activities," for example, lists the calibration of the measurement instrument, the direct monitoring of measurement activities and the corrective measures taken.

All mentioned measures are part of the HACCP Plan of Firma Meica and checked on and documented by the Quality Assurance section of the plant and by officials in Supervision. One cannot recognize a verification deficiency in the HACCP system in the documentation and the actual current practice pursued by Firma Meica. One cannot recognize any system deficiency.

With respect to B.1:

Until now, U.S. authorities had not prescribed any daily supervision; instead, they confined themselves to the supervision requirements of the FSIS representatives, above all for the time during U.S. production (constant supervision of incoming commodities up to shipment of commodities) throughout the time in which no commodities were produced for the U.S. market, in other words, official monitoring was performed only in accordance with the various national or European Union requirements. The just recently established requirement of the FSIS for daily checkups also outside the time during which products are being turned out for the U.S. market has in the meantime been properly taken into account. Accordingly, there has also been an increase in the frequency of monitoring prior to the start of work and during the second shift. According to views held here, the frequency of supervision actually bumps into a limit that remains yet to be justified in a meaningful manner (in-house monitoring) and that would still be economically bearable. Operational supervision for enterprises shipping experts to the USA is done free of charge; this creates a competitive disadvantage for German plants, something that is not compatible with the WTO Agreement according to views held here.

With respect to B.2:

The CCP's are being checked on and they are being monitored by Supervision at the start of work in the plant and are being properly documented. Additional checks are performed in the context of official sampling and external examinations in the state examination bureaus and, moreover, on a random sampling basis; the calibration of the used measurement instruments is checked with officially calibrated instruments at the monitoring points. All of these measures are documented in the reports. Here again, one cannot recognize any shortcoming.

Summarizing, it must be said that the report of the FSIS is entirely too general for anyone to be able to make any specific comments on the individual shortcomings. It is therefore suggested that a more detailed record be prepared for each individual monitored enterprise.

With respect to personnel facilities:

On the basis of new operating agreements (interference in the private sphere), personnel lockers will, effective immediately, be checked twice a year by Quality Assurance in the presence of representatives of the shop committee for hygienic conditions. Monitoring and results are documented.

With respect to Enterprise **A/IV/191 – Abraham Schinken GmbH & Co. KG,** Barssel-Harkebrügge:

The following was challenged accordingly:

1. SSOP
2. HACCP examination of CCP
3. General shortcomings that will be covered in detail.

Comment on 1. SSOP:

In-house documentation is compiled according to the recommendations of the representative of the FSIS on one sheet of paper per day and in the future will be handled by one person and no longer – as in the past – by the particular department head.

The in-house description of shortcomings hereafter will be presented in a more detailed form according to new instruments.

With respect to 2. HACCP:

The hazard analysis has in the meantime been performed including the designation of the anticipated practical use by the consumer.

The in-house verification of two CCP's has been accomplished.

The instruction concerning the review of the way in which the temperature measurement instrument works was supplemented by the addition of official calibration.

The HACCP system has in the meantime been validated.

The products were examined once a month for Listeria; besides, swab samples were taken (environmental exams). The examination results are documented.

With respect to 3. SSOP – General Shortcomings:

Fly screens were placed in the personnel facilities.

The manual scoop that was criticized was replaced by a scoop made of plastic material. Instructions were issued to clean the smoking car and a test paper was prepared. A corresponding cleaning machine was ordered to clean the rods used in suspending the hams. The wooden rods have not yet been completely exchanged against metal rods. A list of measures was drawn up. Overhead cleaning (pipelines, cable strands) was done; the hygiene plan was properly adjusted.

Specially marked waste containers are now available in adequate numbers.

For the slicer room: Effective measures were taken against the formation of condensation water at the evaporators. According to local estimates, the requirements (regulations) of the Reference Guide (status as of January 1998) of the USDA are being complied with.

With respect to Enterprise **A/IV/22 – Gebrüger Abraham GmbH,** Werk Seevetal:

All of the established, mostly minor shortcomings were remedied without question including the monthly checkup by the supervisor.

Concerning hazard analysis:
In chemical hazard analysis during Process Step 1, the national examination program was replaced by official plan samples in the nature of random samples.

With respect to the form entitled "Examination of Meat Raw Materials/Working Instruction," "Examination of Temperature in Meat Raw Materials":
The response when the boundary value is exceeded was revised. After coordination with Production, it was decided to facilitate after-refrigeration up to 7°C. At more than 4°C, the goods are locked in place until a temperature of 4°C has been attained. Documentation is applied upon the reverse side of the form entitled "Examination of Meat Raw Materials."

Documentation regarding as to what is being done, for example, in case of soiled ham or ham that has fallen down, is provided on the form entitled "Examination of Meat Raw Materials."

Regarding the working instruction "Examination of the Hygiene Status Before and After Production" as well as the pertinent forms:
This system was developed as suggested by FSIS. The interval was set at twice a month.

With respect to 4: Description of Work Procedures:
Here, consideration was given to the divisions of Goods Receipt, Salting and Cutting as discussed.

With respect to Enterprise **A/EV/139 Herta**, Werk Neuenkirchen:

Along with the communication from the appropriate authority to the effect that the shortcomings noted have all been remedied, it was announced officially that the enterprise has returned the U.S. permit. The enterprise emphasized the observation that the check on shortcomings necessitated a redrafting of the particular operating sheets of the Nestle Concern. This, among other things, necessitates a revision of the HACCP Plan that is to be done within 12 months.

The enterprise has been stricken from the roster of German enterprises holding export licenses to the USA.

With respect to Enterprise **A/EV/36 Schafft Fleischwerke GmbH,** Ansbach:

1. Sanitizers:

   The facilities for knife sterilization were checked out on a random sample basis by the technical maintenance personnel as part of daily operating checks. There were no complaints.

2. Product contact equipment:

   Personnel employed in the area of the frozen goods transport system as well as personnel responsible for cleaning were briefed accordingly. Random sample checks, conducted in the context of daily operating checkups, did not yield any new objections.

3. Personnel hygiene practices:

   This topic was covered in detail as part of the general personnel training program. The department heads, moreover, were informed on the special requirements contained in the FSIS Regulation and were urged to pay more attention to those provisions.

4. Condemned product control:

   Confiscated material is surrendered (according to regulations) from the enterprise along with a cover letter to the Carcass Elimination Plant. As for the rest, reference is made to the organization structure and regulation of competence of the German Veterinary Service. Accordingly supervision exercised by the official veterinarian according to the Meat Hygiene Law is confined to areas within the supervised enterprise.

5. Free operational/operational sanitation:

   Random sample supervision of production not working for exports to the USA has recently also been instituted as part of the daily operating checkups and is documented in the check lists.

6. HACCP:

   a) The HACCP system was revised and was corrected with regard to the indicated points.

   b) The hazard analysis was performed and the potential hazards were identified.

   c) Supervision is described precisely; the frequencies of supervision have been inserted.

   d) The plan has been validated.

   e) Regarding the verification of the examination procedures, the department heads have now been included. The documentation of the HACCP system states that Listeria

monocytogenes, Salmonella spp. and enteropathogenic E. coli as well as Clostridium botulinum and its toxins must not be detectable in the end product. The products may not contain any risk regarding Staphylococcus aureus and its toxins. Any danger to the consumer from foreign bodies and chemical contamination must be excluded and must remain excluded effectively. The newly developed forms for daily hygiene monitoring as well as for the monitoring of the metal detectors are enclosed.

By request of the enterprise, it is stricken from the roster of German enterprises with export license to the USA.

Conclusion

Enterprises and the particular appropriate veterinary authorities noted rather critically that the Audit Report lists the deficiencies partly in an unsystematic and generalizing fashion. It is therefore suggested that a detailed record of deficiencies be drawn up for each individual enterprise and that duplicate listings of shortcomings be avoided in the summary (in the summary, page 4, point 1, "The development and implementation of HACCP...," point 1 is repeated on page 5; three times on page 5 under points 3, 8 and 13, there is listed the shortcoming "inedible product was not denatured..."). That at least creates the wrong optical impression.

The practice of daily supervision, demanded for the first time by the FSIS during the audit in August 2001, means additional costs for the enterprises to the tune of between 8,000 and 21,000 € per year. In the USA, the Federal Government obviously takes care of these costs; this therefore constitutes a considerable competitive disadvantage for the local meat processing plants. The FSIS is therefore asked to reconsider whether the current procedure is compatible with the WTO Agreement or the Agreement of Equivalence between the European Union and the USA.

[Signature illegible]
Dr. Hoppe

Schafft Fleischwerke Ansbach
Zweigniederlassung der Unilever Bestfoods Deutschland

Metal Detector Monitoring

HACCP Documentation Verification:
CCP No. 1, 5, 10, 11, 13, 17, 18, 24, 25, 27
CCP in Work Division is to be marked by circling the corresponding number

Metal detector monitoring interval: 1x per shift at start of shift
Monitoring of ejection plant: 1x per week at start of week
Calendar week from .....20 to 20
Machine number:

Day	Time	Metal detector	Ejection plant	Signature Examiner	Signature Division Chief
Sunday about	0530 hours				
	1400 hours				
	2230 hours				
Monday about	0530 hours				
	1400 hours				
	2230 hours				
Tuesday about	0530 hours				
	1400 hours				
	2230 hours				
Wednesday about	0530 hours				
	1400 hours				
	2230 hours				
Thursday about	0530 hours				
	1400 hours				
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Friday about	0530 hours				
	1400 hours				
	2230 hours				
Saturday about	0530 hours				
	1400 hours				
	2230 hours				
Prepared by: [signature]		Released by: [Signature]		Date: [Illegible]	

Appendix I

City of Ansbach – Public Order and Street Traffic Bureau

Division of Meat Hygiene

Daily Hygiene Monitoring Fa. Schafft, EZ 54/EV 36											
Month/Year											
Date	Production Division										
	Raw material acceptance	Breakup	Cutting	Spice chamber	Filling	Climate-conditioned chamber	Peeling chamber	Bake snack	Final packaging	Laboratory	Signature Official Veterinarian
1											
2											
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Reviewed by:

State Supervisory Authority

Date Signature Stamp